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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, PHS, HHS

ACTION: Revised Mandatory Guidelines

SUMMARY: The Department of Health and Human Services (HHS) revises some of the scientific and technical guidelines for Federal drug testing programs and revises certain standards for certification of laboratories engaged in urine drug testing for Federal agencies.

EFFECTIVE DATE: September 1, 1994

FOR FURTHER INFORMATION CONTACT: Dr. Donna M. Bush, Chief, Drug Testing Section, Division of Workplace Programs, Substance Abuse and Mental Health Services Administration (SAMHSA), Room 9A-53, 5600 Fishers Lane, Rockville, Maryland 20857, tel. (301) 443-6014.

SUPPLEMENTAL INFORMATION: The Department is revising the guidelines entitled "Mandatory Guidelines for Federal Workplace Drug Testing Programs," (Mandatory Guidelines) which were initially published in the **Federal Register** on April 11, 1988 (53 FR 11979). These Mandatory Guidelines and the revisions are developed in accordance with Executive Order No. 12564 dated September 15, 1986, and section 503 of Pub. L. 100-71, 5 U.S.C. section 7301 note, the Supplemental Appropriations Act for fiscal year 1987 dated July 11, 1987. The revisions to the Mandatory Guidelines incorporate changes based on the comments submitted and the Department's first 5 years of experience in implementing and administering these Guidelines.

BACKGROUND AND SUMMARY OF PUBLIC COMMENTS AND POLICIES OF THE REVISED GUIDELINES

A. Proposed Revised Mandatory Guidelines

The basic purpose of the Mandatory Guidelines is to establish scientific and technical guidelines for Federal agencies' workplace drug testing programs and to establish a certification program for laboratories engaged in urine drug testing for Federal agencies. The proposed revisions published in the **Federal Register** on January 25, 1993 (58 FR 6062), retained the basic requirements in the Mandatory Guidelines published in the Federal Register on April 11, 1988, but as indicated above refined some requirements in order to incorporate changes based on the Department's first 5 years of experience in implementing and administering these Guidelines.

The major changes proposed in the notice published in the **Federal Register** on January 25, 1993, are summarized here to facilitate the discussion of the comments received during the public comment period.

The Department proposed reducing the requirement to collect 60 mL of urine at the collection site to 30 mL. This change was proposed because many times donors have difficulty in providing the 60 mL of urine. In addition, 30 mL is adequate to complete the required testing and satisfy other program requirements.

The Department proposed to revise the specimen collection procedure to allow Federal agencies to use an optional "split specimen" collection procedure. Several Federal agencies have been granted waivers to use split specimen collection procedures during the past 5 years. Establishing a "split specimen" procedure will ensure that each Federal agency will be using the same procedure. The Department believes that appropriate guidance must be provided regarding the minimum acceptable volumes for the split specimens, measuring temperature before a single donor specimen is transferred into two separate specimen bottles, sending both split specimen bottles to the laboratory at the same time to ensure that they are subject to the same shipping and storage conditions, and specifying the procedures for testing Bottle B when the Bottle A specimen is reported positive.

The Department proposed to revise the collection procedure to allow Federal agencies to use an individual of the same gender, other than a collection site employee, to observe the collection of a specimen whenever there is reason to believe the individual may have altered or substituted the specimen. This change is based on the understanding that it is not always possible to have a collection site employee of the same gender observe the collection.

The Department proposed a change to allow a laboratory to use a certifying scientist who is only certified to review initial drug tests which are negative. This could assist in reducing the cost of testing without compromising the reliability of drug testing.

The Department proposed that the initial test level for marijuana metabolites be reduced from 100 ng/mL to 50 ng/mL. This change reflects advances in technology of immunoassay tests for marijuana metabolites.

The Department proposed to allow laboratories to use multiple immunoassay tests for the same drug or drug class. This would allow laboratories to use an initial test and then forward all presumptive positives for a second test by a different immunoassay technique to minimize possible presumptive positives due to the presence of structural analogues in the specimen. In addition, this policy would allow a laboratory to use a different immunoassay for specimens that may be untestable with one immunoassay.

The Department proposed that in order to report a specimen positive for only methamphetamine, the specimen must also contain the metabolite amphetamine at a concentration equal to or greater than 200 ng/mL by the confirmatory test. This proposed requirement would ensure that high concentrations of sympathomimetic amines available in over-the-counter and prescription medications will not be misidentified as methamphetamine.

The Department proposed reducing the number of blind samples a Federal agency must submit each quarter to its contracting laboratory from 10% of all samples to a minimum of 3% (with a maximum of 100 blind samples). This proposed change may significantly reduce the costs associated with maintaining a blind sample program without affecting the Federal agency's ability to monitor a laboratory's performance.

The performance testing sample portion of the laboratory certification program was proposed to be changed by reducing the performance testing (PT) challenges for certified

laboratories from 6 cycles per year to 4 cycles per year. Experience in this and other performance testing programs indicates that 4 cycles per year is sufficient to assess a laboratory's ability to test and report results for performance testing samples.

The Department proposed restricting the types of arrangements that can exist between the Medical Review Officer (MRO) and the laboratory to ensure that a conflict of interest does not exist. The restrictions would require that the agency's MRO not be an employee or an agent of, or have any financial interest in, the laboratory for which the MRO is reviewing drug testing results. Similarly, the laboratory would be prohibited from entering into any agreement with an MRO that could be construed as a conflict of interest.

A new subpart D was proposed which provides detailed procedures for the internal review of a suspension or proposed revocation of a laboratory's certification to perform drug testing. These procedures will ensure and provide a timely and fair review of all suspensions or proposed revocations.

The Department proposed that the written notice of the suspension which is sent to the laboratory, as well as the reviewing official's written decision upholding or denying suspension or proposed revocation under the review procedures in subpart D, would be made available to the public upon request. This provision ensures that the public has access to the documents containing the basis for HHS's actions.

B. Public Comments and the Department's Responses

The Department received 73 public comments on the proposed changes from Federal agencies, individuals, organizations, and companies. About 50% of these supported all or some of the proposed changes. All written comments were reviewed and taken into consideration in the preparation of the revised Mandatory Guidelines. The substantive concerns raised in the public comments and the Department's responses to the comments are set out below. Similar comments are considered together.

1. Definitions

A number of commenters expressed concerns with the definitions in section 1.2. It was suggested that the definition for chain of custody indicate that couriers do not need to document chain of custody while the specimens are in transit to the laboratory. The Department agrees that the Mandatory Guidelines should be clarified to address that issue. Specimens are sealed in packages and any tampering with a sealed specimen would be noticed by the laboratory and documented on the specimen chain of custody. In addition, as a practical matter, couriers, express couriers, and postal service personnel do not have access to the specimen chain of custody form since the form is inside the sealed package. Section 2.2(i) of the Mandatory Guidelines that discusses the transportation of a specimen to a laboratory has been revised to clarify this point.

One commenter recommended that the definitions in the Guidelines conform to the definitions established by the National Committee for Clinical Laboratory Standards (NCCLS) since the proposed definitions may be in conflict with the efforts of that nonprofit, educational organization. The Department fully supports the efforts of this committee to develop standard definitions since a common understanding of definitions is essential for maintaining a high level of performance within laboratory testing programs. The Department has revised the definitions

in section 1.2 to ensure that they are consistent with those proposed currently by NCCLS. The Department has changed the proposed definitions for calibrator, control, and standard as well as included new definitions for donor, specimen, sample, and quality control sample. The Department also made appropriate changes in other sections of the Guidelines to ensure that the terms used were consistent with these new definitions. The Department notes, however, that these changes are not substantive, but rather are technical in nature to clarify the definitions. The Department believes these changes will eliminate the confusion expressed by several other commenters regarding the use of these terms in other sections of the Guidelines.

One commenter believes the proposed definition for the certifying scientist should specifically state that the individual understands chain of custody. The Department intended that the definition of certifying scientist include that the individual have a thorough understanding of chain of custody, since it was proposed that such individual have "training and experience in the theory and practice of all methods and procedures used in the laboratory." See section 1.2. However, in order to prevent any confusion, the definition has been changed to clarify this issue.

One commenter suggested that the Secretary require a certifying scientist to possess at least a masters degree, so they would be equal to experts presented by an employee who is contesting the result in court or in an administrative proceeding. Based on the Department's experience, there are numerous highly qualified individuals serving as certifying scientists who possess bachelors' degrees, and who have the expertise to testify as to the records they have certified. These certifying scientists do not need to be qualified as experts in litigation, as the defense may qualify someone else in the laboratory or outside the laboratory to perform this function, if necessary. Further, the Department believes that requiring higher educational requirements would place an unnecessary burden on the laboratories, as well as eliminate many qualified individuals from serving as certifying scientists.

One commenter believes the requirement to use an Office of Management and Budget (OMB) approved specimen chain of custody form requires the laboratories to use OMB approved laboratory chain of custody forms. This interpretation is incorrect. The Department proposed that such forms be used only for specimen chain of custody forms, not laboratory chain of custody forms. The Department believes that standard specimen chain of custody forms are important to ensure that collection sites have a consistent form so as to reduce any errors or incomplete documentation when filling out the forms.

One commenter noted that the Department's proposed definition of an immunoassay test is ambiguous and does not support the policy that allows using a second immunoassay test for specimens that are presumptively positive for amphetamines. Specifically, the term "initial test" was proposed to be defined as "[a]n immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the class of drugs that requires confirmation." The Department agrees with the commenter that the definition is ambiguous. The Department supports allowing laboratories to perform multiple immunoassay tests for the same drug or drug class. Therefore, the Department has clarified the definition to ensure that further testing is consistent with section 2.4(e)(4) which permits conducting multiple initial tests.

2. Dilution/Adulteration Tests

Several commenters concurred with section 2.1(c) which clarifies that laboratories may conduct dilution/adulteration testing to determine the validity of the specimen while some commenters sought to have the Secretary define the specific tests to be conducted and require

that such tests be performed. The issue regarding the types of dilution/adulteration testing to be performed has been highly controversial among forensic laboratory professionals since there is a lack of data to suggest that dilution/adulteration testing can clearly identify a donor who has intentionally taken a substance to affect the outcome of a drug test or has otherwise diluted or adulterated the specimen. At this time, the Department believes that such testing should remain optional and the selection of tests to be conducted for possible dilution/adulteration and the cutoff levels for such tests, if conducted, should be determined by the laboratories based on their best judgment.

Two commenters requested that the Department allow dilution/adulteration testing to be conducted at the collection site. The Department believes that it is better able to monitor the performance of such testing when it is conducted by laboratory personnel, rather than require agencies to monitor such testing at the collection sites. During the laboratory inspection process, the Department is able to evaluate the laboratories' performance of such testing to ensure that tests are performed properly, chain of custody is not broken, and cross-contamination does not occur from one donor specimen to another which could impact the integrity of a specimen. The MRO can review the results of the dilution/adulteration tests and make a decision on the basis of the test and on his or her interview of the donor to determine whether a medical factor may have contributed to the results of such testing. In addition, disallowing the use of dilution/adulteration testing at the collection site ensures that agency employees are not unnecessarily subject to observed collection and thus protects the privacy of individuals to the maximum extent possible.

3. Specimen Collection Procedure

With regard to the specimen collection procedure, a number of commenters were highly supportive of reducing the required volume of a urine specimen from 60 mL to 30 mL as stated in section 2.2(f)(10). One commenter, however, expressed concern that 30 mL is insufficient when dealing with a specimen that is positive for more than one drug. That may be the case in some cases. Nevertheless, the number of specimens that are positive for more than one drug is very small and most volumes collected generally exceed 30 mL. The Department believes this reduced volume requirement will make it easier for an individual to provide a urine specimen with sufficient volume on the first attempt rather than requiring the collection of a second specimen after drinking a reasonable quantity of liquid. It is noted that the policy of combining additional urine, after drinking a reasonable amount of liquid, with a partial specimen (i.e., an insufficient volume of urine on the first void) has been eliminated. The Department believes the reduced volume requirements will ensure that a sufficient volume is collected on the first void and combining partial specimens will not be necessary.

One commenter expressed concern over the fact that the Mandatory Guidelines did not specify limitations or guidance as to the amount of liquid to be given a donor who could not provide a 30 mL urine specimen. The commenter expressed concerns regarding the possible risk of water intoxication if there is no limit established for the amount of liquid that can be provided. The Department concurs and has changed the example given in section 2.2(f)(10) to read "(e.g., an 8 oz glass of water every 30 minutes, but not to exceed a maximum of 24 oz)." The example provided describes a reasonable amount of liquid to be provided and the Department would expect collection sites to use reasonable care in its determination of the amount of liquid to provide donors.

Several commenters noted that the temperature range stated in the proposed revisions did not agree with the range stated in the introductory discussion of the proposed changes. A notice correcting the error was published in the Federal Register on March 1, 1993. The correct temperature range is "32°-38°/90°-100°F."

There was general agreement that the marginally wider temperature range will not adversely affect the ability to detect a donor who may possibly tamper with the specimen. Two commenters, however, believe that the lower limit of the temperature range should be increased. The Department does not agree with this recommendation. A urine specimen provided in a collection cup that is at room temperature will cool quickly; therefore, a narrow temperature range will significantly increase the number of specimens that will not satisfy the temperature range requirements. This would cause numerous unnecessary collections of second specimens and falsely raise suspicions that many donors have tampered with their specimens.

With regard to the collection of a urine specimen when using direct observation, one commenter suggested that the employee's agency choose the observer if there is no collection site person of the same gender available. The Department agrees and sections 2.2(f)(13), 2.2(f)(16), and 2.2(f)(23) have been revised to include this requirement. The Department believes that the agency will select an individual who will act responsibly and reliably so as not to substantiate any allegation to the contrary by an employee.

One commenter believes that only trained collectors should be involved in the collection procedure, especially when direct observation is required. The Department acknowledges that trained personnel should be involved in the collection of urine specimens; however, it is not always possible to ensure that a trained collection site person of the same gender will be available when a direct observation is required. Allowing the agency to select an individual to act as the observer, when there are unusual circumstances, ensures that the collection will occur promptly and as scheduled rather than delaying the collection unnecessarily.

One commenter believed that observed collection should never be used in any circumstances. The Department disagrees. The Department continues to believe that observed collection is justified and necessary when there exists reasonable suspicion to believe that the donor altered or substituted the specimen. Observed collections do not occur frequently. However, the Department believes that any invasion of a donor's privacy is greatly outweighed by public health and safety concerns in such cases.

One commenter recommended that we refer to the individual providing the urine specimen as the "donor." The Department concurs with the recommendation and has replaced the word "individual," when it refers to the person providing a urine specimen, with the word "donor" throughout the Guidelines. A definition for donor has been included in section 1.2. In addition, the use of the word "donor" is consistent with its use on the specimen chain of custody form.

One commenter suggested that the entire collection procedure be revised substantially to provide more specific guidance to agencies on the collection process. The Department believes the procedure, as described, provides sufficient guidance to the agencies on the collection process, including factors to ensure that urine specimens are collected properly and satisfy chain of custody requirements. The changes made in the Mandatory Guidelines with regard to the single specimen collection procedure and the optional split specimen procedure should clarify the procedures and, thereby, address many of the concerns raised by this commenter without completely revising and expanding the descriptions of the collection procedures.

Many commenters concurred with including an optional split specimen collection procedure. They believed it was important to include split specimens since the Omnibus Transportation Employee Testing Act of 1991, Title V of Pub. L. 102-143, requires using a split specimen collection procedure for industries regulated by the Department of Transportation (DOT). This is particularly important since Federal employees from a number of Departments will be subject to both the requirements of DOT (49 CFR Part 40) and the requirements of the Mandatory Guidelines and Executive Order 12564 (September 15, 1986).

Two commenters suggested allowing the use of two or three containers to collect split specimens. The Department agrees with this recommendation and has revised the collection procedure to indicate clearly that either a specimen bottle or a specimen container may be used when collecting urine specimens. However, when using a split specimen collection procedure, it is not acceptable for a donor to provide the split specimens by urinating directly into both Bottle A and Bottle B. The specimen must be provided by urinating into only one container or into Bottle A. After the temperature is measured, if the specimen was provided directly into Bottle A, an appropriate amount is poured into Bottle B. If a specimen container was used, appropriate amounts are poured from the specimen container into both Bottle A and Bottle B. For split specimen collections, this procedure ensures that the specimens in Bottle A and Bottle B are identical, it is easier to measure the temperature of a single specimen rather than to measure the temperature of two specimens that were collected in separate containers, and it is easier for a donor to provide one specimen in a single container/bottle rather than into two separate bottles.

It was suggested by several commenters that we specify the amount of urine to be poured into Bottle B. We concur with that recommendation and have changed section 2.2(h)(3) of the split specimen procedure to specify that a minimum of 15 mL of urine shall be poured into Bottle B. Since Bottle B will only be tested for a specific substance(s), 15 mL is sufficient to conduct the testing and to allow a sufficient quantity to be retained frozen if Bottle A is reported positive. Additionally, section 2.2(h)(1) has been changed to specify that a minimum of 45 mL of urine is required when using a split specimen collection procedure rather than the 30 mL minimum when using the single specimen collection procedure.

One commenter was concerned with the handling and storage of the split specimen (Bottle B) after the Bottle A specimen is shipped to the laboratory. We agree that the wording in section 2.2(h)(5) of the split specimen collection procedure regarding refrigerating the specimens was confusing and it has been revised. The Department believes that the most efficient and cost effective way to handle split specimens is to send both the Bottle A and Bottle B specimens to the laboratory at the same time including the appropriate specimen chain of custody forms. This procedure will ensure the integrity of both Bottle A and Bottle B. This procedure is also simpler and more cost effective than one which would require the collection site to retain Bottle B specimens until the results for the Bottle A specimens are reported by the MRO to the agency and the agency notifies the collection site to either discard the Bottle B specimens or to ship a specific Bottle B specimen to another certified laboratory. When both specimens are received by the laboratory, Bottle A is normally tested within one day and, if positive, both Bottle A and Bottle B can be placed in secure, refrigerated storage until the confirmatory test is completed. This procedure will ensure that both specimens are treated essentially the same and subject to similar storage conditions until the testing is completed.

Several commenters were concerned with the impact that a failed to reconfirm result on the Bottle B specimen would have on a donor since personnel action may have been taken based on an MRO verified positive result for Bottle A. Although a failed to reconfirm result for Bottle

B requires the MRO to void the test result for Bottle A and an agency may be required to reverse any personnel action that may have been taken, we believe failed to reconfirm reports will occur infrequently and this possibility should not be the basis for an agency to delay any personnel action. The Department believes that removing an employee, for example, from a safety-sensitive position which may impact public health and safety outweighs the minimal possibility that the testing of Bottle B will not reconfirm the presence of a drug or metabolite.

In view of the comments, section 2.2(h)(6) has also been clarified to indicate the MRO's responsibility to report a positive result for Bottle A. When an MRO has verified the test of the first specimen bottle (Bottle A) as a positive result, the MRO must report the result to the agency without waiting for the donor to request that the Bottle B specimen be tested.

Several commenters expressed concern regarding the actions taken when a second laboratory fails to reconfirm the presence of a drug or metabolite in the second specimen bottle (Bottle B) in a split specimen collection. Since the Bottle B specimen is tested without regard to the cutoff levels, the result reported by the second laboratory is not reported as a negative or positive result, but reported as either reconfirmed or failed to reconfirm the presence of a drug or metabolite. The Department agrees that if this situation occurs, an investigation must be conducted. The Department has added this requirement in section 2.2(h)(8) of the Mandatory Guidelines and has required the MRO to notify the donor's agency. In addition, the Federal agency must contact the Secretary and the Secretary will investigate the failed to reconfirm result and attempt to determine the reason for the inconsistent results between Bottle A and Bottle B. HHS will report its findings to the Federal agency and ensure that appropriate action is taken to prevent the recurrence of the failed to reconfirm result.

Some commenters simply did not like permitting Federal agencies to have the option of a split specimen procedure, believing, for example, that the use of a split specimen procedure gives the perception of a lack of confidence in the results when using a single specimen collection, that the additional administrative and collection costs are not justified, and that there is an increased risk of administrative errors.

It should be noted that certain Federal employees are subject to both the Mandatory Guidelines and the Omnibus Transportation Employee Act of 1991, Title V of Pub. L. 102-431, (Omnibus Act) which requires split specimens. Therefore, the agencies must have the flexibility to collect split specimens as required by the Omnibus Act. Since Federal agencies may also request a waiver under section 1.1(e) of the Mandatory Guidelines and the Department has provided a number of agencies with a waiver to permit split specimens during the past 5 years, the Department believes including an optional split specimen collection procedure in the Mandatory Guidelines will ensure consistency among all agencies currently using split specimens and those wanting to implement split specimen collections. In addition, each agency should have the option of treating its employees equally rather than treating its employees under the Omnibus Act differently from the employees only subject to the Mandatory Guidelines.

With regard to the perception that the results from a single specimen collection are unreliable and not adequate to protect employee rights when compared to a split specimen collection, the Department is confident that the results from a single specimen collection are scientifically and legally supportable. This belief is based on the stringent requirements that have been established by the Mandatory Guidelines -- that is, requiring the use of rigorous chain of custody procedures when handling and testing specimens; requiring laboratories to use qualified and trained personnel, validated analytical testing procedures, and extensive internal quality control and quality assurance procedures; requiring laboratories to participate in a

comprehensive certification program that includes performance testing samples and semi-annual inspections; and using MROs to ensure that procedures have been followed as required.

Although the split specimen procedures are designed to minimize administrative errors, the Department acknowledges that any time procedures are modified the risk of administrative errors increases. However, the use of a standard specimen chain of custody form should minimize such errors and the Department, through the inspection process, will monitor the laboratories' procedures in processing split specimens.

The procedures for split specimens are also designed to keep the administrative burden at a minimum. The Department believes that the paperwork for collection sites or laboratories will not increase much since the collection sites will be using a seven-part chain of custody form instead of a six-part form and sending both split specimens to the laboratory at the same time and in the same shipping container. This should minimize the additional cost and administrative burden on both collection sites and laboratories.

One commenter believed that split specimen collections create a potential to reverse results especially if there is a significant variation in the analytical sensitivities of the confirmatory tests used by each of the HHS-certified laboratories. The Department is aware of this potential and has provided guidance to the laboratories with regard to their capability to accurately quantitate and identify drugs at concentrations that are 40 percent of the confirmatory test levels. The Department believes this guidance and challenging laboratories with performance testing samples at these low concentrations will ensure that all laboratories have essentially the same sensitivity for each of the confirmatory tests.

Finally, one commenter requested guidance on whether the donor or agency would be responsible for paying the costs associated with analyzing the split specimen. The Department believes that the decision regarding financial responsibility for testing Bottle B is one the agencies must decide.

4. Certifying Test Results

One commenter stated that the proposed revision to section 2.3(b) that discusses "test validation" did not make it clear that a laboratory may use a certifying scientist who is only certified to review initial drug tests which are negative. Although this is the intent of this section and to ensure that no confusion exists, the title of section 2.3(b) has been changed to read "Certifying Test Results" and that section has been revised to state clearly that a laboratory may designate a certifying scientist(s) that is only qualified to certify results that are negative on the initial test. We note, however, that if a certifying scientist certifies confirmatory test results, the individual must have training and experience in all "procedures relevant to the results that the individual certifies." This includes both initial test and confirmatory test procedures. Changing the title of this section to read "Certifying Test Results" should also ensure that we are referring to the review and certification of specimen test results rather than the results associated with "validating" an analytical procedure before it is used to test specimens. The Department believes there was some confusion associated with the former title of this section.

5. Security and Chain of Custody

One commenter requested that the security requirements in section 2.4(a)(1), as proposed, be revised to allow emergency personnel access to all sections of the laboratory without escorts.

The requirements for security pertain to limiting and documenting access under normal situations and providing escorts for authorized visitors, maintenance, and service personnel. For real emergencies, such as fires, it would be inappropriate to require the laboratory to provide an escort. This section has been changed to ensure that emergency personnel (such as firefighters) can have unescorted access similar to that authorized for inspectors. As suggested by the commenter, it would be acceptable for the laboratory to document the emergency and include, to the extent practicable, dates, time of entry and exit, and purpose of entry for all emergency response personnel. It must be noted that this exception does not apply to emergency "service" personnel, such as manufacturers' technical representatives who are called to repair an instrument or to conduct routine service.

6. Specimen Processing

One commenter noted that the word "standards" had been used incorrectly in section 2.4(d), as proposed, when stating the requirements for each initial and confirmatory batch. The Department concurs and has changed this section to state that each initial and confirmatory batch must satisfy the quality control requirements in sections 2.5(b) and 2.5(c), respectively, rather than using terms such as "standards" and "controls." Additionally, the last sentence of this section has been deleted because it is not entirely correct. Quality control samples must be known to laboratory technicians conducting the testing while only blind performance testing samples are unknown (i.e., the location in the batch, drug or metabolite present, and concentration). The requirements for laboratory blind performance testing samples and agency blind samples are discussed in section 2.5.

7. Marijuana Initial Test Level

Many respondents concurred with lowering the initial test level for marijuana metabolites from 100 to 50 ng/mL as proposed in section 2.4(e). However, one commenter claimed that the lowered cutoff concentration would identify the occasional user. The intent of Federal workplace drug testing programs is to identify individuals who use illegal substances regardless of whether they are regular or occasional users. Lowering the initial test level should increase the ability to detect any use of marijuana.

Another commenter questioned the impact that might result by the lowered cutoff concentration for those individuals who are exposed to passive inhalation (i.e., breathing the smoke exhaled by another individual smoking marijuana cigarettes). The Department does not believe that passive inhalation is a reasonable defense or that significant exposure can occur through passive inhalation to cause a urine specimen to be reported positive. A comprehensive study of passive inhalation conducted at the National Institute on Drug Abuse's Addiction Research Center in Baltimore (see Cone, E.J., et al., Passive Inhalation of Marijuana Smoke: Urinalysis and Room Air Levels of Delta-9-Tetrahydrocannabinol, Journal of Analytical Toxicology, 11: 89-96, 1987) indicates that it takes extensive exposure to extremely high concentrations under unrealistic conditions to cause a positive result; therefore, passive inhalation is not a reasonable explanation for a positive result.

8. Initial and Confirmatory Tests

One commenter believed that the wording in section 2.4(e)(3), as proposed, conflicted with the authority to conduct dilution/adulteration tests as stated in section 2.1(c). The Department agrees that this section needs to be clarified. A laboratory may conduct dilution/adulteration tests on all specimens, whether they are positive or negative, and either before or after conducting the initial test. Section 2.4(e)(3) has been changed to clarify this policy.

Several commenters questioned the use of specimens that test negative on either the initial test or the confirmatory test for the laboratory's internal quality control program as proposed in sections 2.4(e)(3) and 2.4(f)(3). These commenters were concerned that the results may have been affected by such factors as medications that may have been taken, the health of the donors, and possible unknown problems with confirmation, thereby, making these specimens unsuitable as quality control samples. Several of these commenters recommended the use of certified negative urine or, at a minimum, confirming the negative pool by GC/MS prior to its use in a quality control program. In response to these concerns, the Department notes that the laboratory's operation must be consistent with good forensic laboratory practice (see section 3.20(c)) and such practice requires a laboratory to always certify a urine pool as negative before it is used to prepare negative samples or to prepare other quality control samples. If pooled urine does not satisfy the criteria for acceptability, it is discarded. Such certification of the urine will ensure the quality of a laboratory's internal quality control program.

9. Multiple Initial Tests

Two commenters supported the use of multiple initial tests as stated in section 2.4(e)(4), as proposed, while several commenters expressed concern with permitting the use of multiple testing. The Department believes that the use of multiple initial tests may reduce the number of presumptive positives that are forwarded to confirmatory testing that will not be confirmed and may allow obtaining a valid analytical result if a specimen is untestable on one immunoassay test. The use of multiple initial tests has been widely used with regard to testing for amphetamines and this policy should apply to all drugs.

In addition, there are reports that various substances, including prescription medications, can prevent obtaining a valid initial test result when using one immunoassay test. We believe it is appropriate to use a different immunoassay test in order to obtain a valid initial test result before reporting the specimen as "test not performed" and including an appropriate comment on the specimen chain of custody form. To clarify this issue, the example given in section 2.4(e)(4) has been changed to include the use of a second immunoassay test for untestable specimens.

It is noted that the last sentence of section 2.4(e)(4), as proposed, has been deleted since it is redundant with the requirements as stated in the first sentence of the section.

10. 200 ng/mL Amphetamine Reporting Rule

Six commenters concurred with the proposal in sections 2.4(f)(1) and 2.4(g)(2) that require a methamphetamine positive to contain at least 200 ng/mL of amphetamine before reporting the result as positive. Two commenters recommended that the 200 ng/mL rule be dropped entirely because they believed it is no longer relevant and the emphasis should be on improving the quality of the GC/MS confirmatory procedure. Seven commenters held similar views that the 200 ng/mL rule is too conservative and produces too many false negatives and

recommended that it be lowered to either 100 or 50 ng/mL or at least equal to or greater than the limit of detection for amphetamine.

The Department believes that the 200 ng/mL requirement implemented as a temporary policy since December 22, 1990, is a necessary one to prevent false positive test results. On a special set of performance testing samples provided to the laboratories by the program, the Department found that the requirement adequately controlled all of the possible technical problems based on observations of results reported by the laboratories on that set of performance testing samples. The results indicated that a significant number of laboratories experienced chromatographic resolution problems when methamphetamine was present with ephedrine and 2% of the performance testing results evidenced a methamphetamine response when challenged with high concentrations of over-the-counter medications (e.g., ephedrine, pseudoephedrine, or phenylpropanolamine). These results indicated that the 200 ng/mL rule was effective in preventing any false positive results and should be continued. In addition, recent information provided by laboratories regarding their limits of quantitation and their results on performance testing samples that contained very low concentrations of amphetamine and methamphetamine indicate that 200 ng/mL continues to be the lowest concentration that most of the laboratories can reliably identify and quantitate for either methamphetamine or amphetamine. For these reasons, the Department believes using a lower concentration or eliminating the 200 ng/mL rule would increase the possibility for reporting a false positive methamphetamine result.

11. Reporting Results

One commenter was concerned that substituting "certifying scientist" in section 2.4(g)(5), as proposed, for the responsible person was making the certifying scientist responsible for the overall laboratory operations. We believe the commenter did not understand the purpose for changing the wording in this section. The use of "certifying scientist" in this section ensures that the requirement is consistent with current program practice. The responsible person continues to be responsible for the overall operation of the laboratory (see section 2.3(a)); however, section 2.4(g)(5) allows a certifying scientist to sign the external chain of custody form that is sent to the MRO.

12. Calibrators and Controls

One commenter raised concern with the materials used to prepare calibrators and controls which as described in section 2.4(n)(2) only allowed calibrators and controls to be prepared from pure drug standards. The commenter correctly indicated that calibrators and controls were available from other sources. The Department concurs and has revised the sentence to allow calibrators and controls to be prepared not only from pure drug reference materials, but from stock standard solutions obtained from other laboratories, or from commercial manufacturers. This change clarifies that laboratories have the flexibility to obtain "standards" used to prepare the calibrators and controls from different sources.

13. Potential Conflicts of Interest

Several commenters supported the policies in sections 2.4(n)(6) and 2.6(b), as proposed, that restricts the types of relationships between laboratories and Medical Review Officers to

ensure there were no conflicts of interest. There were several comments submitted, however, stating that these requirements were not necessary since there is no evidence that MROs have not acted in the interest of the donor or that current arrangements have adversely affected the ability of an MRO to monitor laboratories. The Department does not question the dedication and integrity of its certified laboratories and the MROs in carrying out their responsibilities and protecting the interests of the Federal agencies and donors. Nevertheless, the Department believes the issue must be addressed.

The MRO plays an essential role in the Federal drug testing program. See generally section 2.6 of the Mandatory Guidelines. The MRO is a licensed physician with a knowledge of substance abuse disorders who verifies whether the tests are positive or negative. In the case of a positive result reported by the laboratory, the Mandatory Guidelines require that the MRO contact the employee and personally interview the employee, i.e., in-person or by telephone, to determine whether alternate medical explanations would explain a positive result. See section 2.6(c). During the course of such interview and possibly through having the specimen retested, the MRO may identify false positive test results. In such a case, the MRO is required to contact the Secretary so that the Department can conduct an investigation into the matter and take whatever action is necessary to prevent such a result from occurring in the future. See section 2.6(g).

Because the MRO plays such an essential role, the Department believes any relationship that may be construed as a potential conflict of interest may be sufficient to undermine the integrity of the program. Every Federal agency, employee, and job applicant must have complete assurance that test results will be thoroughly reviewed and, if errors are discovered, that the MRO will report the error and an appropriate investigation and corrective action will be taken.

14. Laboratory Quality Control Requirements for Initial Tests

There were several comments submitted regarding the requirements in section 2.5(b), as proposed, for quality control samples when conducting the initial test. The commenters believed the proposed requirements were confusing and suggested using different terms to describe the types of quality controls that must be included in each initial test batch. The Department concurs that the quality control requirements in this section were confusing and they have been revised based on the definitions in section 1.2. It should be noted the changes to this section only clarify the requirements for quality control samples; the actual policy has not changed from the original Mandatory Guidelines. See section 2.5(b) of 53 FR 11979, 11984 (April 11, 1988). We have also revised the quality control requirements for each confirmatory test batch in section 2.5(c) using the new definitions in section 1.2 without changing the policy as compared to the original Mandatory Guidelines. See section 2.5(c) of 53 FR 11979, 11985 (April 11, 1988).

In addition, it was noted that there was an error in the requirement that each initial test batch must contain a minimum of 20% quality control samples. A correction stating that 10% was the minimum amount was published in the Federal Register on March 1, 1993.

15. Agency Blind Sample Program

A number of commenters supported reducing the requirements for agency blind samples from 10% to 3% as indicated in section 2.5(d)(2). One commenter suggested retaining the 10%

minimum and one commenter suggested establishing a minimum number of blind samples per quarter for organizations with a small test population. The Department believes the reduced requirement will not have a significant impact on the ability of an agency to evaluate its entire drug testing program; however, there is no prohibition for an agency to use a higher percentage or a higher number of blind samples to be submitted with donor specimens.

The Department has also changed the requirements for the number of blind samples to be submitted with donor specimens during the initial 90-day period of any new contract to conform with reducing the requirements of blind samples as provided by section 2.5(d)(2). Our experience during the past 5 years suggests that it is not necessary to submit large numbers of blind samples to verify the testing conducted by the certified laboratories.

16. Reanalysis Authorized

Two commenters expressed concern with the retesting policy proposed in section 2.6(e) which provided that only the MRO was authorized to order a reanalysis of the original specimen or Bottle B from a split specimen collection. One commenter believes the donor was authorized to request a retest of the original specimen. It is the Department's position that if an MRO cannot verify a positive result for whatever reason, only the MRO is authorized to request the retest of the original specimen since the MRO is the only individual who has all the information necessary to identify a particular specimen in a laboratory.

Another commenter pointed out an inconsistency between the retest policy proposed in this section and the policy proposed for testing Bottle B from a split specimen collection as described in section 2.2(h)(6) which states that only the donor may request through the MRO that the second specimen bottle (Bottle B) be tested. The Department agrees that there is an inconsistency in the proposed policies because we inadvertently referred to the Bottle B specimen in section 2.6(e) rather than the Bottle A specimen. Section 2.6(e) has been changed to clarify that only the MRO may request the retest of either a single specimen or a Bottle A specimen when using a split specimen collection. The procedures for the testing of Bottle B remain as proposed in section 2.2(h)(6) -- that is, only the donor may request through the MRO that Bottle B be tested.

17. Reporting Final Results to the Agency

One commenter suggested that section 2.6(h), as proposed, which clarifies the requirement that the MRO provide written reports to the agency on positive and negative drug test results would significantly increase the administrative costs associated with the program and recommended that the MRO be required to provide written reports to the agency for positive results only. The Department disagrees. Written reports from the MRO to the agency on all specimens tested ensures that all specimens have been tested and the results of all specimens have been reviewed by the MRO. In addition, the Department believes that this requirement for written reports to the agency does not prevent the MRO from reporting several results on the same correspondence sent to the agency and, therefore, should not significantly affect the cost associated with the MRO review of drug testing results.

18. Certified Laboratories Notifying Private Sector Clients

Two commenters were concerned that the policy in section 3.4 did not adequately ensure that a laboratory would inform clients if and when the laboratory did not satisfy the certification requirements. The Department concurs that a laboratory must inform its clients when its certification has been suspended. Since the program began, this notification has been required and is set out in the suspension letter that is sent to the laboratory.

However, the intent of the requirement in section 3.4 that certified laboratories clearly inform clients when procedures followed do not conform to the Mandatory Guidelines is not related to suspension and/or proposed revocation actions. The purpose is to ensure that unregulated, private sector clients are aware that the laboratory may be using procedures that are not subject to or in accordance with the Mandatory Guidelines. The Department believes that a certified laboratory must not use its certification to promote itself as such if, in fact, it uses procedures that do not comply with the Mandatory Guidelines for such clients. This section has been revised to clarify this requirement.

19. Performance Testing Program

There were several comments submitted regarding changing the performance testing (PT) program from a bimonthly program to a quarterly program as stated in various sections of subpart C. One commenter disagreed with changing the performance testing program to a quarterly program because this would prolong the recertification process and suggested that a monthly PT program would be more appropriate. The Department has no intention of changing the initial certification procedures or to change the procedures when a laboratory has been suspended and must successfully analyze performance testing samples prior to having the suspension lifted. In addition, the Department believes a monthly PT program does not allow sufficient time for a laboratory to receive its results on a set of PT samples, analyze its performance, and initiate appropriate corrective action before the next cycle of PT samples.

One commenter was concerned that adopting a quarterly PT program without changing the criteria for determining acceptable performance, as set out in section 3.19, would increase the period for evaluating a laboratory's performance to 9 months. The Department concurs that the criteria for determining acceptable performance, that is, performance on 3 consecutive quarterly PT cycles, would unduly lengthen the time before corrective action may be taken. Since the total number of PT samples in 2 cycles of the quarterly PT program will be essentially the same as those for 3 cycles of the bimonthly PT program, it is appropriate to establish acceptable performance criteria based on performance over 2 consecutive cycles of quarterly PT samples. All criteria in section 3.19 that pertain to evaluating the performance of certified laboratories have been changed to evaluate acceptable performance over 2 consecutive cycles rather than over 3 consecutive cycles, which retains the 6-month evaluation period.

One commenter agreed with the change in section 3.19(b)(4), as proposed, that would allow a certified laboratory to have one quantitative result greater than 50% from the target value without requiring program action against the laboratory. However, the commenter is concerned that the cause for the error may not be investigated since program action is not taken against the laboratory. The Department did not intend that this change would prevent any investigation into the cause for the error or that the laboratory would not be required by the Department to make a concerted effort to determine the cause for the error and to take appropriate corrective action.

One commenter believes that the overall costs for the certification program may be decreased without compromising the high quality of the program by increasing the PT challenges

to a monthly program and decreasing the maintenance inspections to once a year. The Department disagrees with this proposal because it is important to inspect laboratories at least every six months to ensure that the laboratory has continued to satisfy the requirements of the Mandatory Guidelines and for the inspectors to review the results reported for the PT samples. If corrective action is necessary, it will be more timely than if inspections were on a yearly basis. In addition, the existence of a significant problem over a long period of time would possibly jeopardize the results of many more personnel specimens.

20. Corrective Action by Certified Laboratories

Several commenters expressed concern that section 3.12(c), as proposed, would give the Secretary the authority to review all results and activities associated with a laboratory's testing of specimens for private sector, unregulated clients. This was not the intent and the section has been changed to indicate that the Secretary has authority to review results for specimens collected for private sector clients that were tested by the certified laboratory under the Mandatory Guidelines to the extent necessary to ensure the full reliability of drug testing for Federal agencies.

21. Recertification

One commenter was concerned with the policy contained in section 3.16, as proposed, because the commenter believed the procedure to regain certification after the laboratory's certification has been revoked would be prolonged given that the maintenance PT program has been reduced to a quarterly program. The commenter misunderstood that provision. The Department has not changed the initial certification procedure (section 3.16) under which a laboratory that had its certification revoked must proceed to regain certification. Thus, such a laboratory will proceed as in the past and must satisfactorily perform in each phase of the initial certification process. However, the first sentence of section 3.16 has been changed to indicate that the recertification policy applies only when a laboratory has its certification revoked.

22. Inspection Performance

One commenter was concerned that the meaning of the phrase "consistent with good forensic laboratory practice" in section 3.20(c), as proposed, was too subjective. The commenter believes that each inspection team interprets laboratory's procedures differently, thereby, what is acceptable during one inspection may be unacceptable during the next inspection. We do not concur with this assessment of the inspection process. Although there is some inherent subjectivity in the inspection process when applying certain criteria under the Mandatory Guidelines, the inspectors are provided clear guidance on what is to be inspected and what is acceptable and unacceptable. The Department requires trained, qualified inspectors to use a comprehensive checklist consisting of some 300 questions to evaluate a laboratory's procedures. They are asked to respond "yes" or "no" to the questions and then provide comments if the answer is unacceptable. This checklist ensures that each inspector is reviewing essentially all of the same laboratory documents and results. The inspection reports are reviewed by the Department to ensure that program requirements and policies are applied consistently among all laboratories. In addition, it is the responsibility of each laboratory to review the Mandatory

Guidelines, to be aware of what is to be inspected by reviewing the checklist and other program documents, to correct deficiencies, and to use good forensic laboratory practice in its testing program.

One commenter suggested that the word "all" be deleted from the second sentence in section 3.20(c), as proposed, because a laboratory is not required to correct "all" deficiencies identified by the inspectors. We concur with the comment and have deleted the word "all." The Department's policy has always been to include minor deficiencies or concerns in the critique developed from the inspection reports and give the laboratory the option to take whatever additional corrective action it deems appropriate for these minor deficiencies or concerns.

23. Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

One commenter suggests that the definition of appellant in section 4.2, as proposed, is unclear and believes that the review procedures only apply when there is a proposed revocation. The Department disagrees with this position. The Department believes that principles of fairness necessitate allowing laboratories to seek internal reviews not only of proposed revocations but also internal reviews of immediate suspensions.

24. Other Minor Changes

In addition to the changes discussed above, there were several minor changes made in other sections. The acronym "MRO" has been added to the definition for Medical Review Officer in section 1.2. Since the original Guidelines were published, the "MRO" acronym has become a common and accepted way to refer to a physician performing this function. We have replaced "Medical Review Officer" with "MRO" throughout the Guidelines.

Section 2.5(d)(4) was changed to clarify that an agency shall investigate any unsatisfactory blind performance testing results and submit its findings to HHS rather than HHS conducting the initial investigation. The Department believes the agency must gather all pertinent information and investigate the reason before HHS is contacted to continue the investigation and to ensure that the laboratory has taken corrective action.

Section 2.6(c) has been simplified to require the MRO to send results only to the designated person in the agency rather than to both agency's Employee Assistance Program and to the agency's management official. The Department believes that the agency should have the discretion to determine who should receive results.

Section 3.3 was clarified to read that a laboratory must satisfy all pertinent provisions of the Guidelines in order to maintain certification while the original requirement only addressed satisfying the provisions in order to qualify for certification.

Section 3.15(b) was revised to conform with the review procedure in new subpart D which allows laboratories the opportunity for an informal review of a program action within 30 days of the date the laboratory received the notice, or if seeking an expedited review, within 3 days of the date the laboratory received the notice.

Two commenters noted that section 3.18(b) referred to a subset of PT samples as "directed specimens" rather than as "retest samples" which is current program terminology. We concur with the comment submitted and have revised the section to refer to these PT samples as "retest samples."

Other appropriate minor editorial changes have been made for clarity and consistency.

Information Collection Requirements

Any comments related to the Paperwork Reduction Act of 1980 may be sent to the HHS Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 3001, New Executive Office Building, Washington, D.C. 20503.

Information collection and recordkeeping requirements which would be imposed on laboratories engaged in urine drug testing for Federal agencies concern quality assurance and quality control; security and chain of custody; documentation; reports; performance testing; and inspections as set out in sections 3.7, 3.8, 3.10, 3.11, 3.17, and 3.20. To facilitate ease of use and uniform reporting, a specimen chain of custody form has been developed as referenced in sections 1.2, 2.2(c), and 2.2(f).

The information collection and recordkeeping requirements contained in these Mandatory Guidelines have been submitted to the Office of Management and Budget for review under section 3504(h) of the Paperwork Reduction Act of 1980.

Dated: February 7, 1994

Philip R. Lee
Assistant Secretary for Health.

Dated: March 16, 1994

Donna E. Shalala
Secretary.

The Mandatory Guidelines as revised are hereby adopted in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71. For the public's convenience the Mandatory Guidelines as revised are set out in full as follows:

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS

Subpart A - General

Subpart B - Scientific and Technical Requirements

Subpart C - Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Subpart D - Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

Authority: E.O. 12564 and Sec. 503 of Pub. L. 100-71.

Subpart A - General

Section 1.1 Applicability

(a) These mandatory guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) And any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

(b) Subpart C of these Guidelines (which establishes laboratory certification standards) applies to any laboratory which has or seeks certification to perform urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only laboratories certified under these standards are authorized to perform urine drug testing for Federal agencies.

(c) The Intelligence Community, as defined by Executive Order No. 12333, shall be subject to these Guidelines only to the extent agreed to by the head of the affected agency.

(d) These Guidelines do not apply to drug testing conducted under legal authority other than E.O. 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

(e) Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary. In requesting approval for a deviation, an agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale therefor. The Secretary may approve the request upon a finding of good cause as determined by the Secretary.

(f) Agencies shall purchase drug testing services only from laboratories certified by HHS or an HHS-recognized certification program in accordance with these Guidelines.

Section 1.2 Definitions

For purposes of these Guidelines the following definitions are adopted:

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Calibrator. A solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

Certifying Scientist. An individual with at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and

practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience shall also include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to test systems being out of control-limits or detecting aberrant test or quality control results.

Chain of Custody. Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an Office of Management and Budget (OMB) approved specimen chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt by the laboratory an appropriate laboratory chain of custody form(s) account for the specimens and samples within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or sample is handled or transferred and identifying every individual in the chain of custody.

Collection Site. A place designated by the agency where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection Site Person. A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function.

Confirmatory Test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

Control. A sample used to monitor the status of an analysis to maintain its performance within desired limits.

Donor. The individual from whom a urine specimen is collected.

Initial Test (also known as Screening Test). An immunoassay test to eliminate "negative" urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Laboratory Chain of Custody Form. The form(s) used by the testing laboratory to document the security of the specimen and all aliquots of the specimens during testing and storage by the laboratory. The form, which may account for an entire laboratory test batch, shall include the names and signatures of all individuals who accessed the specimens or aliquots and the date and purpose of the access.

Medical Review Officer (MRO). A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Quality Control Sample. A sample used to evaluate whether or not the analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative urine samples, and blind samples are collectively referred to as "quality control samples" and each as a "sample."

Reason to Believe. Reason to believe that a particular individual may alter or substitute the urine specimen as provided in section 4(c) of E.O. 12564.

Sample. A representative portion of a urine specimen or quality control sample used for testing.

Secretary. The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

Specimen. The portion of urine that is collected from a donor.

Specimen Chain of Custody Form. An OMB approved form used to document the security of the specimen from time of collection until receipt by the laboratory. This form, at a minimum, shall include specimen identifying information, date and location of collection, name and signature of collector, name of testing laboratory, and the names and signatures of all individuals who had custody of the specimen from time of collection until the specimen was prepared for shipment to the laboratory.

Standard. A reference material of known purity or a solution containing a reference material at a known concentration.

Section 1.3 Future Revisions

In order to ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the **Federal Register**.

Subpart B - Scientific and Technical Requirements

Section 2.1 The Drugs

(a) The President's Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

(1) Federal agency applicant and random drug testing programs shall at a minimum test for marijuana and cocaine;

(2) Federal agency applicant and random drug testing programs are also authorized to test for opiates, amphetamines, and phencyclidine; and

(3) When conducting reasonable suspicion, accident, or unsafe practice testing, a Federal agency may test for any drug listed in Schedule I or II of the CSA.

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency testing in paragraph (a) of this section. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drugs covered under Schedule I or II of the CSA.

(c) Urine specimens collected pursuant to Executive Order 12564, Pub. L. 100-71, and these Guidelines shall be used only to test for those drugs included in agency drug-free

workplace plans and may not be used to conduct any other analysis or test unless otherwise authorized by law except if additional testing is required to determine the validity of the specimen. Urine that tests negative by initial or confirmatory testing may, however, be pooled for use in the laboratory's internal quality control program.

(d) These Guidelines are not intended to limit any agency which is specifically authorized by law to include additional categories of drugs in the drug testing of its own employees or employees in its regulated industries.

Section 2.2 Specimen Collection Procedures

(a) *Designation of Collection Site*. Each agency drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory.

(b) *Security*. Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(c) *Chain of Custody*. Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) *Access to Authorized Personnel Only*. No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored.

(e) *Privacy*. Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular donor may alter or substitute the specimen to be provided.

(f) *Integrity and Identity of Specimen*. Agencies shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and on the specimen chain of custody form can identify the donor from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When a donor arrives at the collection site, the collection site person shall request the donor to present photo identification. If the donor does not have proper photo identification, the collection site person shall contact the supervisor of the donor, the coordinator of the drug testing program, or any other agency official who can positively identify the donor. If the donor's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the donor fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to

tamper with or adulterate the donor's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet.

(5) The donor shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the donor shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate the specimen.

(7) The collection site person shall give the donor a clean specimen bottle or specimen container. The donor may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance on the specimen chain of custody form.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A person of the same gender as the donor shall accompany the donor into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the donor not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the donor, the collection site person shall determine the volume of urine in the specimen bottle/container.

(i) If the volume is greater than 30 milliliters (mL), the collection site person will proceed with step (11) below.

(ii) If the volume is less than 30 mL and the temperature is within the acceptable range specified in step (13) below, the specimen is discarded and a second specimen shall be collected. The donor may be given a reasonable amount of liquid to drink for this purpose (e.g., an 8 oz glass of water every 30 min, but not to exceed a maximum of 24 oz). If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(iii) If the volume is less than 30 mL and the temperature is outside the acceptable range specified in step (13) below, a second specimen shall be collected using the procedure specified in step (13) below.

(11) After the specimen has been provided and submitted to the collection site person, the donor shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure only the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of the specimen is outside the range of 32°-38°C/90°-100°F, that is a reason to believe that the donor may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer

if there is no collection site person of the same gender available. A donor may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the donor may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the specimen chain of custody form.

(15) All specimens suspected of being adulterated or diluted shall be forwarded to the laboratory for testing.

(16) When there is any reason to believe that a donor may have altered or substituted the specimen to be provided, another specimen shall be obtained as soon as possible under the direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collection site person of the same gender available.

(17) Both the donor and the collection site person shall keep the specimen bottle/container in view at all times prior to its being sealed and labeled. If the specimen is transferred from a specimen container to a specimen bottle, the collection site person shall request the donor to observe the transfer of the specimen and the placement of the tamper-evident seal/tape on the bottle. The tamper-evident seal may be in the form of evidence tape, a self-sealing bottle cap with both a tamper-evident seal and unique coding, cap and bottle systems that can only be sealed one time, or any other system that ensures any tampering with the specimen will be evident to laboratory personnel during the accessioning process.

(18) The collection site person and the donor shall be present at the same time during procedures outlined in paragraphs (f)(19)-(f)(22) of this section.

(19) The collection site person shall place securely on the specimen bottle an identification label which contains the date, the donor's specimen number, and any other identifying information provided or required by the agency.

(20) The donor shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter on the specimen chain of custody form all information identifying the specimen.

(22) The donor shall be asked to read and sign a statement on the specimen chain of custody form certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(23) Based on a reason to believe that the donor may alter or substitute the specimen to be provided, a higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under direct observation. The person directly observing the specimen collection shall be of the same gender. The agency shall select the observer if there is no collection site person of the same gender available.

(24) The collection site person shall complete the specimen chain of custody form.

(25) The urine specimen and specimen chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26) While any part of the above chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person leaves his or her work station

momentarily, the urine specimen and specimen chain of custody form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

(g) *Collection Control.* To the maximum extent possible, collection site personnel shall keep the donor's specimen bottle within sight both before and after the donor has urinated. After the specimen is collected, it shall be properly sealed and labeled. A specimen chain of custody form shall be used for maintaining control and accountability of each specimen. The date and purpose shall be documented on a specimen chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) *Split Specimens.* An agency may, but is not required to, use a split specimen method of collection. If the urine specimen is split into two specimen bottles (hereinafter referred to as Bottle A and Bottle B) the following procedure shall be used:

(1) The donor shall urinate into either a specimen bottle or specimen container. The collection site person, in the presence of the donor, after determining specimen temperature, pours the urine into two specimen bottles that are labeled Bottle A and Bottle B or, if Bottle A was used to collect the specimen, pours an appropriate amount into Bottle B. A minimum of 45 mL of urine is required when using a split specimen procedure, i.e., 30 mL for Bottle A and 15 mL for Bottle B.

(2) The Bottle A specimen, containing a minimum of 30 mL of urine, is to be used for the drug test. If there is no additional urine available for the second specimen bottle (Bottle B), the first specimen bottle (Bottle A) shall nevertheless be processed for testing.

(3) A minimum of 15 mL of urine shall be poured into the second specimen bottle (Bottle B).

(4) All requirements of this part shall be followed with respect to Bottle A and Bottle B, including the requirements that a copy of the chain of custody form accompany each bottle processed under split sample procedures.

(5) The collection site shall send the split specimens (Bottle A and Bottle B) at the same time to the laboratory that will be testing the Bottle A specimen.

(6) If the test of the first specimen bottle (Bottle A) is verified positive by the MRO, the MRO shall report the result to the agency. Only the donor may request through the MRO that the second specimen bottle (Bottle B) be tested in an HHS-certified laboratory for presence of the drug(s) for which a positive result was obtained in the test of the first specimen bottle (Bottle A). The MRO shall honor such a request if it is made within 72 hours of the donor's having received notice that he or she tested positive. The result of this test is transmitted to the MRO without regard to the cutoff levels used to test the first specimen bottle (Bottle A).

(7) Any action taken by a Federal agency as a result of an MRO verified positive drug test (e.g., removal from performing a safety-sensitive function) may proceed whether Bottle B is or is not tested.

(8) If the result of the test on the second specimen bottle (Bottle B) fails to reconfirm the result reported for Bottle A, the MRO shall void the test result for Bottle A and the donor shall re-enter the group subject to random testing as if the test had not been conducted. The MRO shall notify the Federal agency when a failed to reconfirm has occurred and the agency shall contact the Secretary. The Secretary will investigate the failed to reconfirm result and attempt to determine the reason for the inconsistent results between Bottle A and Bottle B. HHS will report

its findings to the agency including recommendations and/or actions taken to prevent the recurrence of the failed to reconfirm result.

(i) *Transportation to Laboratory.* Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment, for example, specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. The collection site personnel shall ensure that the specimen chain of custody form is enclosed within each container sealed for shipment to the drug testing laboratory. Since specimens are sealed in packages that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the package during transit.

Section 2.3 Laboratory Personnel

(a) *Day-to-Day Management.*

(1) The laboratory shall have a responsible person (RP) to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispeciality laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory’s having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those

personnel. The procedure manual shall be reviewed, signed, and dated by this responsible person whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in section 2.4(n)(1))

(6) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

(b) *Certifying Test Results.* The laboratory's urine drug testing facility shall have a certifying scientist(s), as defined in section 1.2, who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate certifying scientists that are qualified to certify only results that are negative on the initial test and certifying scientists that are qualified to certify both initial and confirmatory tests.

(c) *Day-to-Day Operations and Supervision of Analysts.* The laboratory's urine drug testing facility shall have an individual(s) to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) *Other Personnel.* Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory's urine drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluation and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

Section 2.4 Laboratory Analysis Procedures

(a) *Security and Chain of Custody.*

(1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals

whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of the Secretary or emergency personnel (e.g., firefighters and medical rescue teams), all authorized visitors and maintenance and service personnel shall be escorted at all times. The laboratory shall maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors, maintenance, and service personnel accessing secured areas.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.*

(1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the specimen chain of custody forms attached to the shipment shall be immediately reported to the agency and shall be noted on the specimen chain of custody forms which shall accompany the specimens while they are in the laboratory's possession.

(2) Specimen bottles will normally be retained within the laboratory's accession area until all analyses have been completed. Aliquots and laboratory chain of custody forms shall be used by laboratory personnel for conducting initial and confirmatory tests while the original specimen and specimen chain of custody form remain in secure storage.

(c) *Short-Term Refrigerated Storage.* Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) *Specimen Processing.* Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall satisfy the quality control requirements in sections 2.5 (b) and (c), respectively.

(e) *Initial Test.*

(1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

	Initial Test Level (ng/mL)
Marijuana metabolites.....	50
Cocaine metabolites.....	300
Opiate metabolites.....	300*
Phencyclidine.....	25
Amphetamines.....	1,000

[*] 25 ng/mL if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed initial test methods, testing levels, and proposed performance test program.

(3) Specimens that test negative on all initial immunoassay tests will be reported negative. No further testing of these negative specimens for drugs is permitted and the specimens shall either be discarded or pooled for use in the laboratory's internal quality control program.

(4) Multiple initial tests (also known as rescreening) for the same drug or drug class may be performed provided that all tests meet all Guideline cutoffs and quality control requirements (see section 2.5(b)). Examples: a test is performed by immunoassay technique "A" for all drugs using the HHS cutoff levels, but presumptive positive amphetamines are forwarded for immunoassay technique "B" to eliminate any possible presumptive positives due to structural analogues; a valid analytical result cannot be obtained using immunoassay technique "A" and immunoassay technique "B" is used in an attempt to obtain a valid analytical result.

(f) *Confirmatory Test*.

(1) All specimens identified as positive on the initial test shall be confirmed for the class(es) of drugs screened positive on the initial test using gas chromatography/mass spectrometry (GC/MS) at the cutoff values listed in this paragraph. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "exceeds the linear range of the test."

	Confirmatory Test Level (ng/mL)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	150
Opiates	
Morphine	300
Codeine	300
Phencyclidine	25
Amphetamines	
Amphetamine	500
Methamphetamine[3]	500

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid
[2] Benzoylecgonine
[3] Specimen must also contain amphetamine at a concentration $\geq$ 200 ng/mL

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed confirmatory test methods, testing levels, and proposed performance test program.

(3) Specimens that test negative on confirmatory tests shall be reported negative. No further testing of these specimens for drugs is permitted and the specimens shall either be discarded or pooled for use in the laboratory's internal quality control program.

(g) *Reporting Results.*

(1) The laboratory shall report test results to the agency's MRO within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by a certifying scientist who satisfies the requirements described by the definition in section 1.2. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the agency, and the drug testing laboratory specimen identification number.

(2) Except as otherwise provided by this subsection, the laboratory shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug. For amphetamines, to report a specimen positive for methamphetamine only, the specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL by the confirmatory test. If this criterion is not met, the specimen must be reported as negative for methamphetamine.

(3) The MRO may request from the laboratory and the laboratory shall provide quantitation of test results. The MRO may not disclose quantitation of test results to the agency but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the MRO a certified copy of the original chain of custody form signed by a certifying scientist.

(6) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

Initial Testing:

(i) Number of specimens received;

(ii) Number of specimens reported out; and

(iii) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines

Confirmatory Testing:

(i) Number of specimens received for confirmation;

(ii) Number of specimens confirmed positive for:

Marijuana metabolite
Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for Federal drug testing programs when requested by HHS or any Federal agency for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the agency in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) *Long-Term Storage.* Long-term frozen storage (-20°C or less) ensures that positive urine specimens will be available for any necessary retest. Unless otherwise authorized in writing by the agency, drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an agency may request the laboratory to retain the specimen for an additional period of time. If no such request is received, the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

(i) *Retesting of a Specimen* (i.e., the reanalysis by gas chromatography/mass spectrometry of a specimen previously reported positive or the testing of Bottle B of a split specimen collection). Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(j) *Subcontracting*. Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the agency. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in these Guidelines.

(k) *Laboratory Facilities.*

(1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(2) Laboratories certified in accordance with Subpart C of these Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) *Inspections.* The Secretary, any Federal agency utilizing the laboratory, or any organization performing laboratory certification on behalf of the Secretary may reserve the right to inspect the laboratory at any time. Agency contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the agency to conduct unannounced inspections. In addition, prior to the award of a contract the agency may carry out preaward inspections and evaluation of the procedural aspects of the laboratory's drug testing operation.

(m) *Documentation.* The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by HHS or by any Federal agency for which laboratory

services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody forms; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) *Additional Requirements for Certified Laboratories.*

(1) *Procedure Manual.* Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) *Calibrators and Controls*. Laboratory calibrators and controls shall be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers. The calibrators and controls shall be properly labeled as to content and concentration. The standards (e.g., pure reference materials, stock standard solutions, purchased standards) shall be labeled with the following dates: when received (if applicable); when prepared or opened; when placed in service; and expiration date.

(3) *Instruments and Equipment.*

(i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks, and instructions for major troubleshooting and repair. Records shall be available on preventive maintenance.

(4) *Remedial Actions.* There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) *Personnel Available to Testify at Proceedings*. A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on positive urinalysis results reported by the laboratory.

(6) *Restrictions*. The laboratory shall not enter into any relationship with an agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an agency use a specific MRO.

Section 2.5 Quality Assurance and Quality Control.

(a) *General.* Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) *Laboratory Quality Control Requirements for Initial Tests.* Each analytical run of specimens to be screened shall include:

(1) Sample(s) certified to contain no drug (i.e., negative urine samples);

(2) Positive control(s) fortified with drug or metabolite;

(3) At least one positive control with the drug or metabolite at or near the threshold (cutoff);

(4) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known calibrators, those values will be used to calculate sample data;

(5) A minimum of 10 percent of the total specimens and quality control samples in each analytical run shall be quality control samples; and

(6) One percent of each run, with a minimum of at least one sample, shall be the laboratory's blind quality control samples to appear as normal samples to the laboratory analysts.

Implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen shall be documented.

(c) *Laboratory Quality Control Requirements for Confirmation Tests.* Each analytical run of specimens to be confirmed shall include:

(1) Sample(s) certified to contain no drug (i.e., negative urine samples);

(2) Positive calibrator(s) and control(s) fortified with drug or metabolite; and

(3) At least one positive control with the drug or metabolite at or near the threshold (cutoff).

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of a donor's specimen shall also be documented.

(d) Agency Blind Sample Program.

(1) Agencies shall only purchase blind quality control materials that: (a) have been certified by immunoassay and GC/MS and (b) have stability data which verifies those materials' performance over time.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test samples to each laboratory it contracts with in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 200 blind samples) and thereafter a minimum of 3 percent blind samples (up to a maximum of 100 blind samples) submitted per quarter.

(3) Approximately 80 percent of the blind quality control samples shall be negative (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the agency is testing.

(4) The agency shall investigate any unsatisfactory blind performance test sample results and submit its findings to the Secretary. The Secretary shall continue the investigation to ensure

that the laboratory has corrected the cause of the unsatisfactory performance test result. A report of the Secretary's investigative findings and the corrective action taken by the laboratory shall be sent to the agency contracting officer. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory is engaged in urine drug testing and coordinate any necessary action.

(5) Should a false positive error occur on a blind performance test sample and the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test sample and the error is determined to be a technical or methodological error, the laboratory shall submit all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the Responsible Person. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. The Secretary has the option of revoking (section 3.13) or suspending (section 3.14) the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

Section 2.6 Reporting and Review of Results.

(a) *Medical Review Officer Shall Review Results.* An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the MRO prior to the transmission of results to agency administrative officials.

(b) *Medical Review Officer - Qualifications and Responsibilities.* The MRO shall be a licensed physician with knowledge of substance abuse disorders. The MRO may be an employee of the agency or a contractor for the agency; however, the MRO shall not be an employee or agent of or have any financial interest in the laboratory for which the MRO is reviewing drug testing results. Additionally, the MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest. The role of the MRO is to review and interpret positive test results obtained through the agency's testing program. In carrying out this responsibility, the MRO shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the donor, review of the donor's medical history, or review of any other relevant biomedical factors. The MRO shall review all medical records made available by the donor when a confirmed positive test could have resulted from legally prescribed medication. The MRO shall not, however, consider the results of urine specimens that are not obtained or processed in accordance with these Guidelines.

(c) *Positive Test Result.* Prior to making a final decision to verify a positive test result, the MRO shall give the donor an opportunity to discuss the test result with him or her. Following verification of a positive test result, the MRO shall report the result to the agency's official designated to receive results.

(d) *Verification for Opiates; Review for Prescription Medication.* Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence--in addition to the urine test--of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. This requirement does not apply if the confirmatory procedure for opiates confirms the presence of 6-monoacetylmorphine since the presence of this metabolite is proof of heroin use.

(e) *Reanalysis Authorized*. Should any question arise as to the accuracy or validity of a positive test result, only the MRO is authorized to order a retest of a single specimen or the Bottle A specimen from a split specimen collection. Such retests are authorized only at laboratories certified under these Guidelines.

(f) *Result Consistent with Legal Drug Use.* If the MRO determines there is a legitimate medical explanation for the positive test result, he or she shall take no further action and report the test result as negative.

(g) *Result Scientifically Insufficient.* Additionally, the MRO, based on review of inspection reports, quality control data, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the MRO may request a retest of the original specimen before making this decision. (The MRO may request that the retest be performed by the same laboratory or, as provided in section 2.6(e), that an aliquot of the original specimen be sent for a retest to an alternate laboratory which is certified in accordance with these Guidelines.) The laboratory shall assist in this review process as requested by the MRO by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the agency. The MRO shall report to the Secretary all negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

(h) *Reporting Final Results.* The MRO shall report the final results of the drug tests in writing and in a manner designed to ensure confidentiality of the information.

Section 2.7 Protection of Employee Records.

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101-24.104, all laboratory contracts shall require that the contractor comply with the Privacy Act, 5 U.S.C. 522a. In addition, laboratory contracts shall require compliance with patient access and confidentiality provisions of section 503 of Pub. L. 100-71. The agency shall establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover both the agency's and the laboratory's records of employee urinalysis results. The contract and the Privacy Act System of Records shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

Section 2.8 Individual Access to Test and Laboratory Certification Results.

In accordance with section 503 of Pub. L. 100-71, any Federal employee who is the subject of a drug test shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

Subpart C - Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Section 3.1 Introduction.

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

Section 3.2 Goals and Objectives of Certification.

(a) *Uses of Urine Drug Testing.* Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations indicated in sections 2.4(e) and 2.4(f).

(b) *Need to Set Standards; Inspections.* Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set which laboratories engaged in Federal employee urine drug testing must meet in order to achieve maximum accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. The qualifying evaluation will involve three rounds of performance testing plus an on-site inspection. Maintenance of certification requires participation in a quarterly performance testing program plus periodic, on-site inspections. One inspection following successful completion of a performance testing regimen is required for initial certification. This must be followed by a second inspection within 3 months, after which biannual inspections will be required to maintain certification.

(c) *Urine Drug Testing Applies Analytical Forensic Toxicology.* The possible impact of a positive test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen must be treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and advice of a qualified forensic toxicologist, or individual with equivalent qualifications (both training and experience) to address the specific needs of the

Federal drug testing program, including the demands of chain of custody of specimens, security, proper documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

Section 3.3 General Certification Requirements.

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification under these standards.

Section 3.4 Capability to Test for Five Classes of Drugs.

To be certified, a laboratory must be capable of testing for at least the following five classes of drugs: marijuana, cocaine, opiates, amphetamines, and phencyclidine using the initial immunoassay and quantitative confirmatory GC/MS methods specified in these Guidelines. The certification program will be limited to the five classes of drugs (sections 2.1(a)(1) and (2)) and the methods (sections 2.4(e) and (f)) specified in these Guidelines. The laboratory will be surveyed and performance tested only for these methods and drugs. Certification of a laboratory indicates that any test result reported by the laboratory for the Federal Government meets the standards in these Guidelines for the five classes of drugs using the methods specified. Certified laboratories must clearly inform all unregulated, private clients when their specimens are being tested using procedures that are different from those for which the laboratory is certified (i.e., testing specimens not under the Guidelines).

Section 3.5 Initial and Confirmatory Capability at Same Site.

Certified laboratories shall have the capability, at the same laboratory site, of performing both initial immunoassays and confirmatory GC/MS tests (sections 2.4(e) and (f)) for marijuana, cocaine, opiates, amphetamines, and phencyclidine and for any other drug or metabolite for which agency drug testing is authorized (sections 2.1(a)(1) and (2)). All positive initial test results shall be confirmed prior to reporting them.

Section 3.6 Personnel.

Laboratory personnel shall meet the requirements specified in section 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

Section 3.7 Quality Assurance and Quality Control.

Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed

to monitor the conduct of each step of the process of testing for drugs as specified in section 2.5 of these Guidelines.

Section 3.8 Security and Chain of Custody.

Laboratories shall meet the security and chain of custody requirements provided in section 2.4(a).

Section 3.9 One-Year Storage for Confirmed Positives.

All confirmed positive specimens shall be retained in accordance with the provisions of section 2.4(h) of these Guidelines.

Section 3.10 Documentation.

The laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in section 2.4(m).

Section 3.11 Reports.

The laboratory shall report test results in accordance with the specifications in section 2.4(g).

Section 3.12 Certification.

(a) *General.* The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified any laboratory that is certified by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Criteria.* In determining whether to certify a laboratory or to accept the certification of an HHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria:

(1) The adequacy of the laboratory facilities;

(2) The expertise and experience of the laboratory personnel;

(3) The excellence of the laboratory's quality assurance/ quality control program;

(4) The performance of the laboratory on any performance tests;

(5) The laboratory's compliance with standards as reflected in any laboratory inspections; and

(6) Any other factors affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

(c) *Corrective Action by Certified Laboratories.* A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification. The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary shall have the authority to issue directives to any laboratory suspending the use of certain analytical procedures when necessary to protect the

integrity of the testing process; ordering any laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through proficiency testing; ordering any laboratory to send aliquots of urine specimens to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

Section 3.13 Revocation.

(a) *General.* The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by an HHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results.

(b) *Factors to Consider.* The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or laboratory inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

(c) *Period and Terms.* The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

Section 3.14 Suspension.

(a) *Criteria.* Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug testing for Federal agencies. The Secretary may also accept suspension of certification by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Period and Terms.* The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

Section 3.15 Notice.

(a) *Written Notice.* When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the

suspension or proposed revocation by facsimile mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) *Opportunity for Informal Review*. The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart D contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) *Effective Date.* A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) *HHS-Recognized Certification Program.* The Secretary's responsibility under this section may be carried out by an HHS-recognized certification program in accordance with these Guidelines.

(e) *Public Notice.* The Secretary will publish in the Federal Register the name, address, and telephone number of any laboratory that has its certification suspended or revoked under section 3.13 or section 3.14, respectively, and the name of any laboratory which has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart D.

Section 3.16 Recertification.

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under section 3.13(a) or the reviewing official's decision under section 4.9(e) or 4.14(a), a laboratory which has had its certification revoked may apply for certification in accordance with this section. In order to be certified, the laboratory shall meet the criteria of section 3.12(b), as well as all other requirements of these Guidelines, including the successful participation in three cycles of performance testing (sections 3.17(b) and 3.19(a)) and a laboratory inspection (sections 3.2(b) and 3.20). Once certified, the laboratory must undergo a second inspection within three months, after which biannual inspections will be required to maintain certification (section 3.2(b)), as well as participation in the quarterly performance testing program (sections 3.1(b) and 3.17(c)).

Section 3.17 Performance Testing (PT) Requirement for Certification.

(a) *An Initial and Continuing Requirement.* The PT program is a part of the initial evaluation of a laboratory seeking certification (both PT and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) *Three Initial Cycles Required.* Successful participation in three cycles of testing shall be required before a laboratory is eligible to be considered for certification.

(c) *Four Challenges Per Year.* After certification, laboratories shall be challenged with at least 10 PT samples on a quarterly cycle.

(d) *Laboratory Procedures Identical for Performance Test and Routine Employee Specimens.* All procedures associated with the handling and testing of the PT samples by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine laboratory specimens, unless otherwise specified.

(e) *Blind Performance Test.* Any certified laboratory shall be subject to blind PT samples (see section 2.5(d)). Performance on blind PT samples shall be at the same level as for the open or non-blind PT samples.

(f) *Reporting - Open Performance Test.* The laboratory shall report results of open PT samples to the certifying organization in the same manner as specified in section 2.4(g)(2) for routine specimens.

Section 3.18 Performance Test Samples Composition.

(a) *Description of the Drugs.* PT samples shall contain those drugs and metabolites which each certified laboratory must be prepared to assay in concentration ranges that allow detection of the analytes by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of recent drug users. For some drug analytes, the sample composition will consist of the parent drug as well as major metabolites. In some cases, more than one drug class may be included in one sample, but generally no more than two drugs will be present in any one sample in order to imitate the type of specimen which a laboratory normally encounters. For any particular PT cycle, the actual composition of kits going to different laboratories will vary but, within any annual period, all laboratories participating will have analyzed the same total set of samples.

(b) *Concentrations.* PT samples (as differentiated from blind quality control samples) shall be spiked with the drug classes and their metabolites that are required for certification (marijuana, cocaine, opiates, amphetamines, and phencyclidine) with concentration levels set by, but not limited to, one of the following schema: (1) at least 20 percent above the cutoff limit for either the initial assay or the confirmatory test, depending on which is to be evaluated; (2) below the cutoff limit as retest samples (for GC/MS quantitation); and, (3) below the cutoff limit for special purposes. Some PT samples may be identified for GC/MS assay only (retest samples). Blanks shall contain less than 2 ng/mL of any of the target drugs. These concentration and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use. Finally, PT samples may be constituted with interfering substances.

Section 3.19 Evaluation of Performance Testing.

(a) *Initial Certification.*

(1) An applicant laboratory shall not report any false positive result during PT for initial certification. Any false positive will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade level of 90 percent for the three cycles of PT required for initial certification, i.e., it must correctly identify and confirm 90

percent of the total drug challenges. Any laboratory which achieves a score on any one cycle of the initial certification such that it can no longer achieve a total grade of 90 percent over the three consecutive PT cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values for at least 80 percent of the total drug challenges which are ±20 percent or ±2 standard deviations (whichever range is larger) of the calculated reference group mean. Failure to achieve 80 percent will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative values that differ by more than 50 percent from the calculated reference group mean. Any quantitative values that differ by more than 50 percent will result in disqualification.

(5) For any individual drug, an applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least 50 percent of the total drug challenges. Failure to successfully quantitate at least 50 percent of the challenges for any individual drug will result in disqualification.

(b) *Ongoing Testing of Certified Laboratories.*

(1) *False Positives and Procedures for Dealing with Them.* No false drug identifications are acceptable for any drugs for which a laboratory offers service. Under some circumstances a false positive test may result in suspension or revocation of certification. The most serious false positives are by drug class, such as reporting THC in a blank specimen or reporting cocaine in a specimen known to contain only opiates. Misidentifications within a class (e.g., codeine for morphine) are also false positives which are unacceptable in an appropriately controlled laboratory, but they are clearly less serious errors than misidentification of a class. The following procedures shall be followed when dealing with a false positive:

(i) The agency detecting a false positive error shall immediately notify the laboratory and the Secretary of any such error.

(ii) The laboratory shall provide the Secretary with a written explanation of the reasons for the error within 5 working days. If required by paragraph (b)(1)(v) below, this explanation shall include the submission of all quality control data from the batch of specimens that included the false positive specimen.

(iii) The Secretary shall review the laboratory's explanation within 5 working days and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary may direct the laboratory to take corrective action to minimize the occurrence of the particular error in the future and, if there is reason to believe the error could have been systematic, may require the laboratory to review and reanalyze previously run specimens.

(v) If the error is determined to be a technical or methodological error, the laboratory shall submit to the Secretary all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the laboratory's responsible person. Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include any drugs a laboratory certified under these Guidelines must be prepared to assay. The laboratory shall immediately notify the agency if any result on a specimen that has been retested must be corrected because the criteria for a positive are not satisfied. The Secretary may suspend or revoke the laboratory's certification for all drugs or for only the drug or drug class in which the error occurred.

However, if the case is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, the Secretary may decide to take no further action.

(vi) During the time required to resolve the error, the laboratory shall remain certified but shall have a designation indicating that a false positive result is pending resolution. If the Secretary determines that the laboratory's certification must be suspended or revoked, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or any recertification process is complete.

(2) *Requirement to Identify and Confirm 90 Percent of Total Drug Challenges.* In order to remain certified, laboratories must successfully complete four cycles of PT per year. Failure of a certified laboratory to maintain a grade of 90 percent over the span of two consecutive PT cycles, i.e., to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges, may result in suspension or revocation of certification.

(3) *Requirement to Quantitate 80 Percent of Total Drug Challenges at ±20 Percent or ±2 Standard Deviations.* Quantitative values obtained by a certified laboratory for at least 80 percent of the total drug challenges must be ±20 percent or ±2 standard deviations (whichever range is larger) of the appropriate reference or peer group mean as measured over two consecutive PT cycles.

(4) *Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean.* After achieving certification a laboratory is permitted one quantitative result differing by more than 50% from the target value within two consecutive cycles of PT. More than one error of this type within two consecutive PT cycles may result in a suspension or proposed revocation.

(5) *Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug Challenges for Any Individual Drug.* For any individual drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(2), (b)(3), and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) *Procedures When Requirements in Paragraphs (b)(2) - (b)(5) of this Section Are Not Met.* If a certified laboratory fails to maintain a grade of 90 percent over the span of two consecutive PT cycles after initial certification as required by paragraph (b)(2) of this section or if it fails to successfully quantitate results as required by paragraphs (b)(3), (b)(4), or (b)(5) of this section, the laboratory shall be immediately informed that its performance fell under the 90 percent level or that it failed to quantitate test results successfully and how it failed to quantitate successfully. The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and evidence that the source of the poor performance has been corrected. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) *80 Percent of Participating Laboratories Must Detect Drug.* A laboratory's performance shall be evaluated for all samples for which drugs were spiked at concentrations

above the specified performance test level unless the overall response from participating laboratories indicates that less than 80 percent of them were able to detect a drug.

(d) *Participation Required.* Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of certification.

Section 3.20 Inspections.

(a) *Frequency.* Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of three qualified inspectors, at least two of whom have been trained as laboratory inspectors, shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall quality of the laboratory setting for the purposes of certification to conduct urine drug testing. Inspection reports may also contain recommendations to the laboratory to correct deficiencies noted during the inspection.

(b) *Inspectors.* The Secretary shall establish criteria for the selection of inspectors to ensure high quality, unbiased, and thorough inspections. The inspectors shall perform inspections consistent with the guidance provided by the Secretary. Inspectors shall document the overall quality of the laboratory's drug testing operation.

(c) *Inspection Performance.* The laboratory's operation shall be consistent with good forensic laboratory practice and shall be in compliance with these Guidelines. It is the laboratory's responsibility to correct deficiencies identified during the inspection and to have the knowledge, skill, and expertise to correct deficiencies consistent with good forensic laboratory practice. Consistent with sections 3.13 and 3.14, deficiencies identified at inspections may be the basis for suspending or revoking a laboratory's certification.

Section 3.21 Results of Inadequate Performance.

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in sections 3.13 and 3.14 of these Guidelines.

Section 3.22 Listing of Certified Laboratories.

A **Federal Register** listing of laboratories certified by HHS will be updated and published periodically. Laboratories which are in the applicant stage of HHS certification are *not* to be considered as meeting the minimum requirements in these Guidelines. A laboratory is not certified until HHS has sent the laboratory an HHS letter of certification.

Subpart D - Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory.

Section 4.1 Applicability.

These procedures apply when:

(a) The Secretary has notified a laboratory in writing that its certification to perform urine drug testing under these Mandatory Guidelines for Federal Workplace Drug Testing Programs has been suspended or that the Secretary proposes to revoke such certification.

(b) The laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 4.2 Definitions.

Appellant: Means the laboratory which has been notified of its suspension or proposed revocation of its certification to perform urine drug testing and has requested an informal review thereof.

Respondent: Means the person or persons designated by the Secretary in implementing these Guidelines (currently the National Laboratory Certification Program is located in the Division of Workplace Programs, Substance Abuse and Mental Health Services Administration).

Reviewing Official: Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 4.3 Limitation on Issues Subject to Review.

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of the Mandatory Guidelines shall not be subject to review under these procedures.

Section 4.4 Specifying Who Represents the Parties.

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

Section 4.5 The Request for Informal Review and the Reviewing Official's Response.

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 4.6 Abeyance Agreement.

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 4.7 Preparation of the Review File and Written Argument.

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform urine drug testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 4.8 Opportunity for Oral Presentation.

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 4.9 Expedited Procedures for Review of Immediate Suspension.

(a) *Applicability.* When the Secretary notifies a laboratory in writing that its certification to perform urine drug testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following: (1) a review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically, and (2) a written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with section 4.8(c) and will conduct the oral presentation in accordance with the procedures of sections 4.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in section 4.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile or overnight mail.

Section 4.10 Ex parte Communications.

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 4.11 Transmission of Written Communications by Reviewing Official and Calculation of Deadlines.

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

Section 4.12 Authority and Responsibilities of Reviewing Official.

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 4.13 Administrative Record.

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 4.14 Written Decision.

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the Federal Register. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the Federal Register.

Section 4.15 Court Review of Final Administrative Action; Exhaustion of Administrative Remedies.

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under section 4.9(e) or 4.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

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